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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,986	09/08/2000	Edwin L Madison	225/049	2665

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,986

Applicant(s)

MADISON ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 6 and 7 is/are allowed.
- 6) ☒ Claim(s) 2, 4, and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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The Response filed on July 28, 2003 as paper 26, is acknowledged. Claims 1-2, and 4-7 are pending and are the subject of this Office Action.

OFFICE ACTION

1. Rejections

1.1. 35 USC, section 112, second paragraph

Rejection of claim 4 for the use of the term "selectively" is withdrawn in the light of Applicants' arguments, because the term is defined on page 11, line 20 as meaning that IC_{50} for a compound when it inhibits martiptase is at least two times lower than when said compound inhibits factor Xa or thrombin.

1.2. 35 USC, section 112, first paragraph

1.2.1. Rejection for lack of written description

Claim 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Neither the claims nor specification describe any inhibitor that has an IC_{50} of 100 nM or less. In addition, the IC_{50} for inhibition of Xa and thrombin are not disclosed, thus one skilled in the art cannot say which, according to Applicants definition of the term "selectively", of the chemicals selectively inhibit martiptase.

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In conclusion, claims 2,4, and 5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Traversing this rejection Applicants argue, "this rejection is not well taken. Applicants submit that they have complied with the written description requirement of the first paragraph of Section 112. They have described the use of certain specific compounds for decreasing martipase or MTSP1 activity and described an assay for determining those compounds which have IC_{50} for martipase or MTSP1 of 100nM or less. Applicants submit that such description clearly demonstrates that they were in possession of the claimed invention at the time the application was filled" (page 3, line 7).

Applicants' argument has been fully considered but is found not persuasive for the following reasons. Applicants provided enough guidance so that one skilled in the art could perform IC_{50} determination himself/ herself. Therefore the claims are not rejected for lack of enablement. However, Applicants did not themselves teach any IC_{50} values for the recited compounds to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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3.4. 35 USC section 102

Rejection of claim 1 and 4, as being anticipated by US Patents No. 5,492,895 issued to Vlasuk et al. on Feb. 20, 1996; 5,696,231 issued to Abelman et al. on Dec. 9, 1997; No. 5, 776, 027, issued to Abelman et al. on July 1998, is withdrawn because Applicants arguments are found persuasive.

4. Conclusion

Claims 1, 6 and 7 are allowed for reasons indicated in the previous Office Action, paper No.18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner


TEJCHAND SAIDHA
PRIMARY EXAMINER